



Presentation to:

FDA Home Use Workshop

Labeling and Training for Home Use –
Focus on User Performance

May 24, 2010

Understanding Human Capabilities

Memory, learning, reaction time, performance, perception, and conditions that produce errors.

Formal Testing of Human-Machine Interaction



Identifying Mental Models

Understanding how users think about the system.

Modeling the User's Role in the System



Labeling & Training

Displays

Alarms

Controls



Labeling

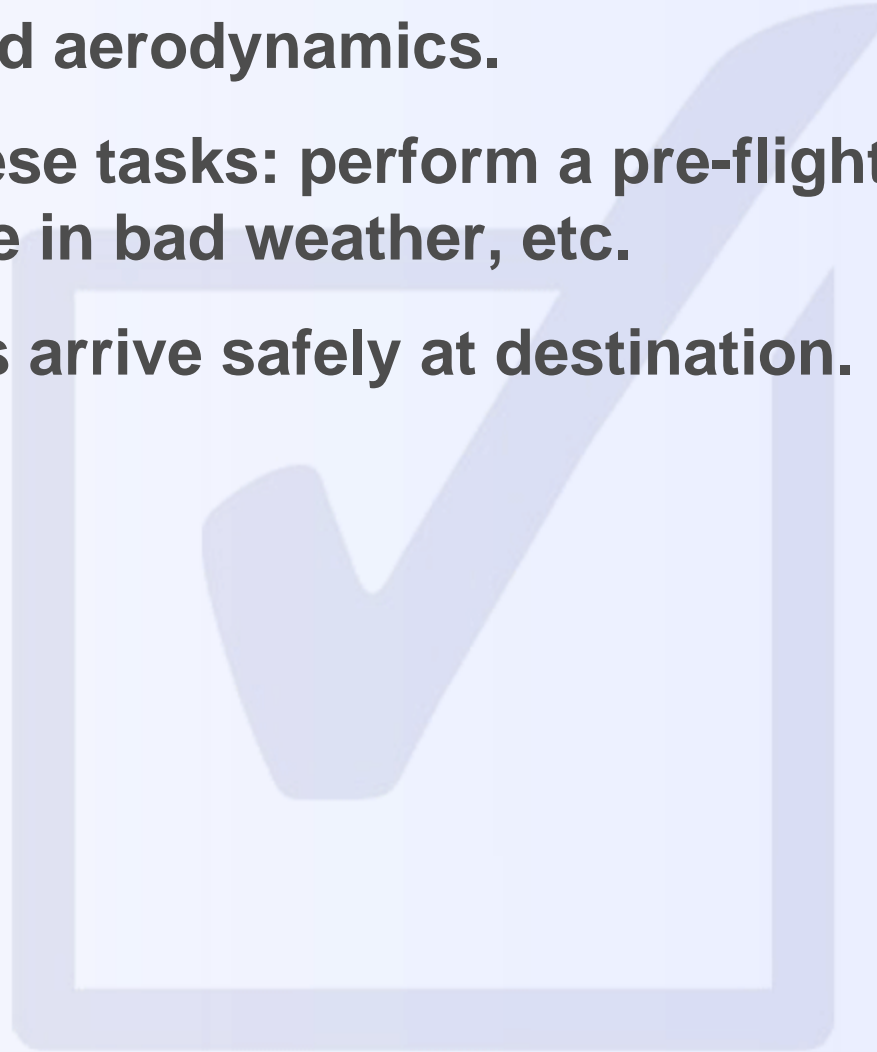
Graphical User Interface (GUI)

Ergonomics

- 1. Labeling and training cannot substitute for a well designed device.**
- 2. A systematic approach to influencing performance is better than a random approach.**
- 3. We want to maximize the effectiveness of how we influence performance as efficiently as possible**
- 4. The purpose of labeling and training is to support safe and accurate user performance to produce outcomes of value.**

What Do You Value Most?

- ☐ I understand aerodynamics.
- ☐ I can do these tasks: perform a pre-flight check, land a plane in bad weather, etc.
- ☐ Passengers arrive safely at destination.

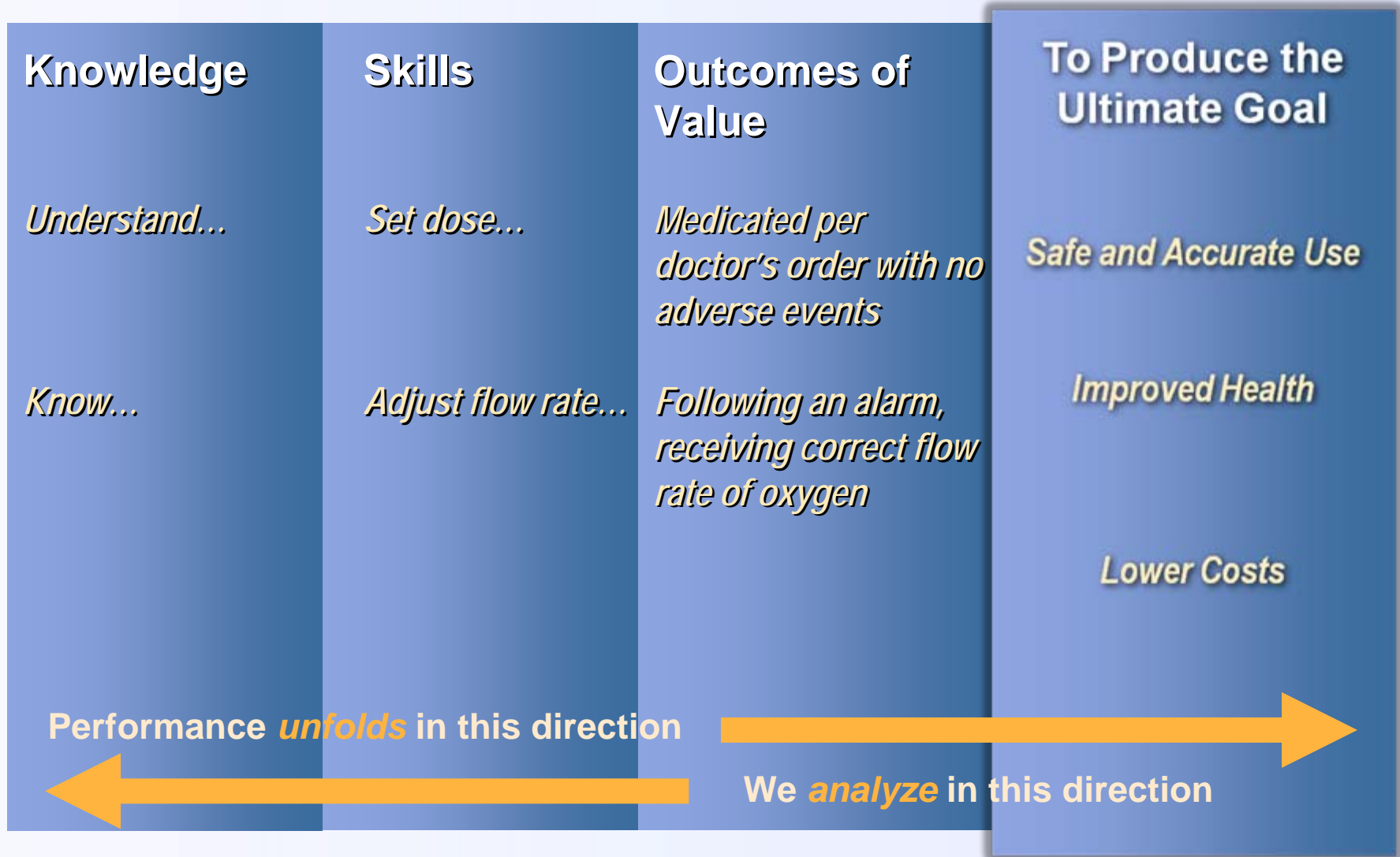


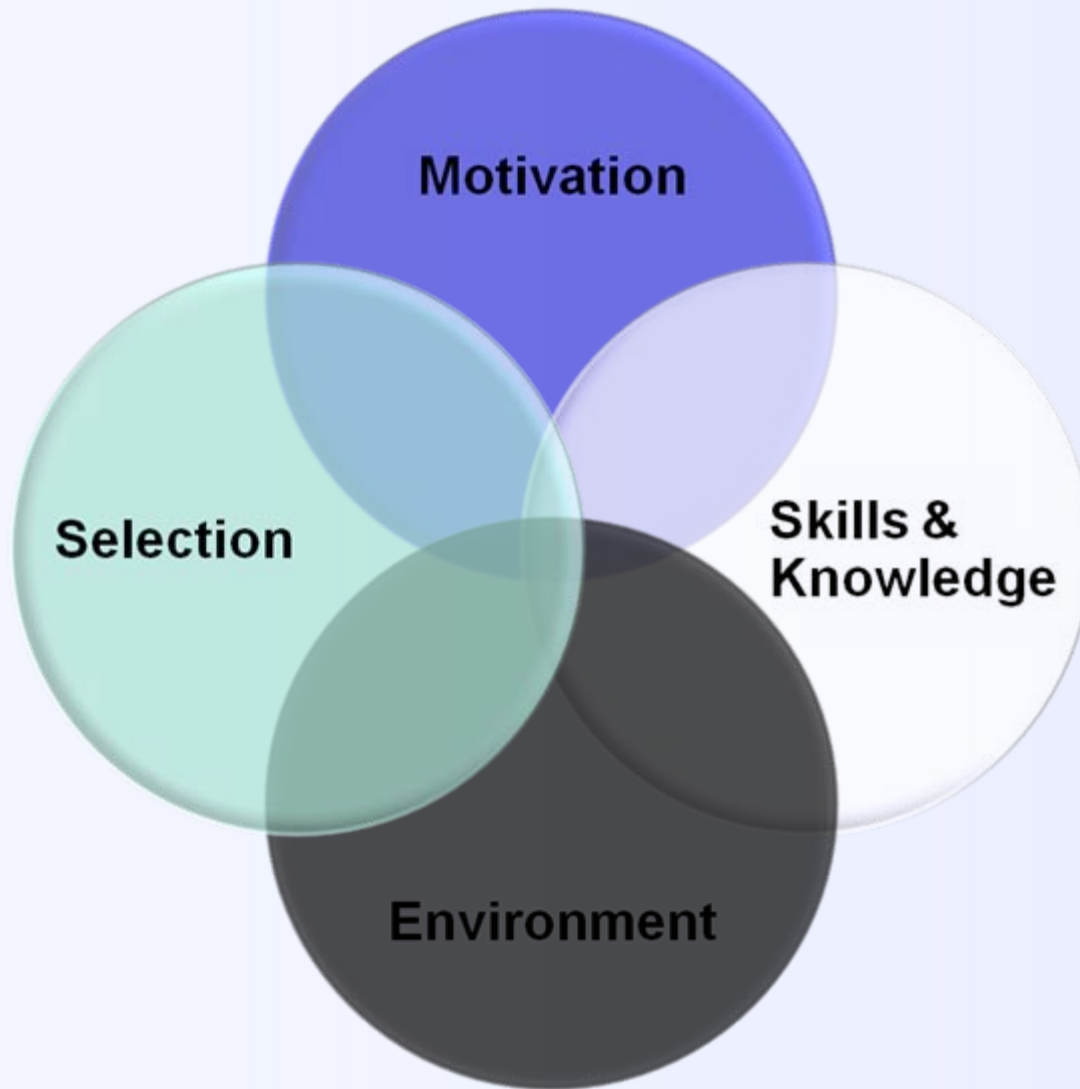
What Do You Value Most?

- ☐ I understand the importance of administering the right dose of medication.
- ☐ I can do these tasks: setup the pump, set the correct dose at the correct flow, etc.
- ☐ Mrs. Jones is medicated per doctor's orders with no adverse events.

- ☐ I know how to adjust the respiration settings.
- ☐ I can do these tasks: set respiratory rate, set tidal volume, adjust flow rate, etc.
- ☐ Following a low pressure alarm, baby Chris is receiving oxygen at the correct flow rate and at the correct pressure.

What is Performance?





Memory Influences Retention

Some define long term memory as anything longer than 18 seconds.



1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18

Three Ways to Achieve Performance



Training



**User
Guides/Quick
Guides**



**Training
Plus
Guides**

Training – a planned experience when there is

Performance Aid – a storage place for information other than user memory that gives direction on when and how to perform, is intended to be accessed in real-time and is written at a level of detail to minimize trial and error.

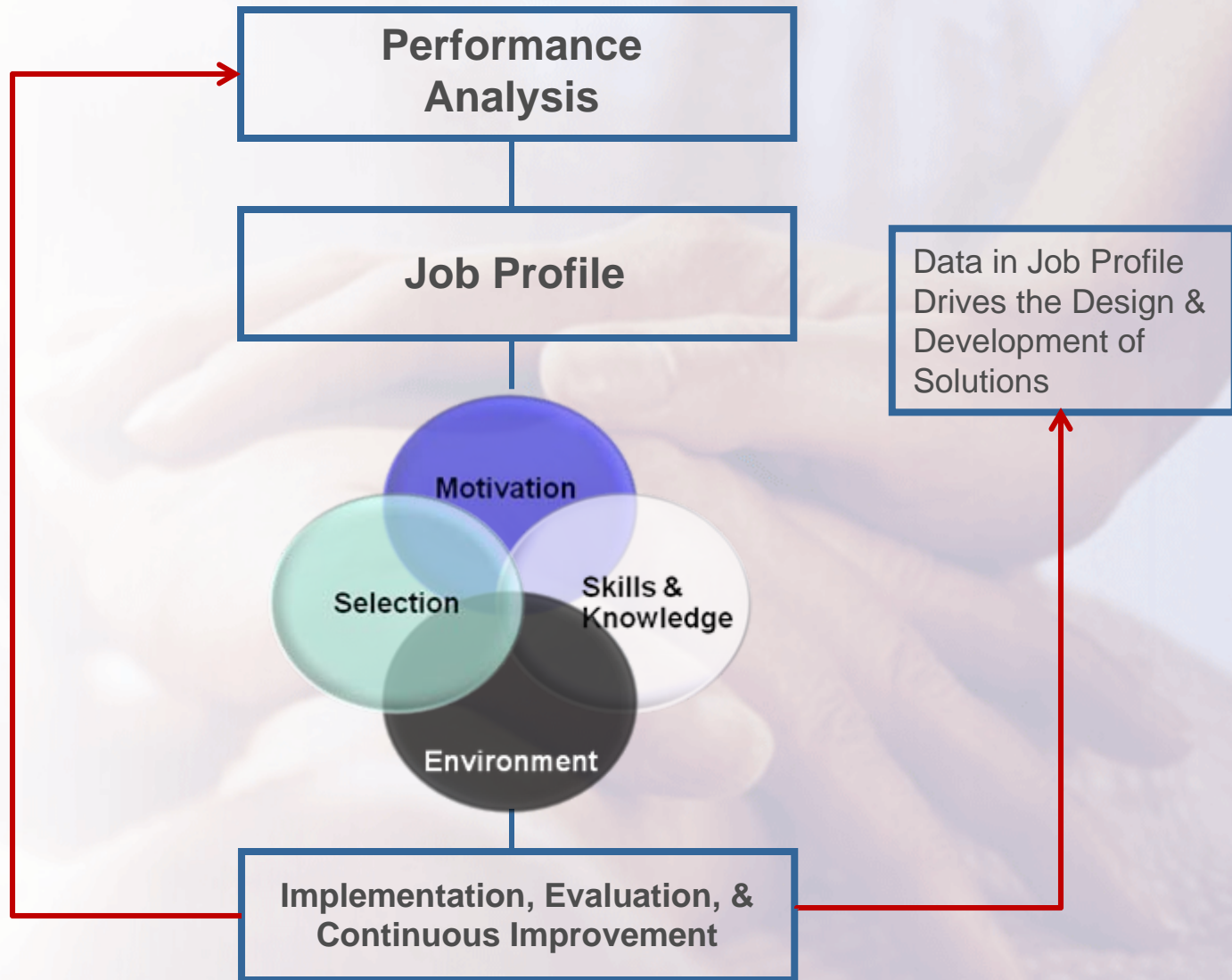


**Safe and Accurate
User Performance**

1. Prior to each use, inspect product for damage. **DO NOT** use if any damage is found.
2. Parents should carefully inspect electrodes, lead wires, and power cords and plugs.
3. A 'simple' 5 step set-up process is followed by one Warning and four Notes including:
 1. A mask should not be used in the pulse dose delivery mode as it may not fit to the face well enough to allow the conserving device to sense inhalation efforts. Also, the therapeutic effect of the oxygen conserving device would not be realized, as the dose of oxygen would be diluted in the mask prior to inhalation.



- The formal method of systematically **observing** and recording representative members of the **target audience** performing **real tasks** with a real or simulated product and assessed against **measurable criteria**
- Focus on **use error** - *“Act or omission of an act that results in a different outcome than intended by the manufacturer or expected by the USER, which may result from a mismatch situation between USER, man-machine interface, task and/or environment.”*
AAMI HE74:2001
- See AAMI Standard HE75: Human Factors for Medical Devices 2010





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